REMARKS

The Specification has been amended to recite relevant domestic priority data and to address certain informalities noted in the Office Action. Claims 1-20 are cancelled without prejudice or disclaimer. New claims 21-32 have been added and a summary of these claims follows.

The subject matter of former claim 18 has been rewritten in new independent claim 21 to recite a method for determining the presence or absence of a phosphatidylinositol-3,4-diphosphate (PI-3,4-P2) in a test sample, where the antibody used in the method is "a monoclonal antibody labeled with a marker or a variable region thereof labeled with a marker, which specifically binds to an antigenic determinant comprising an inositol group and a glycerol backbone on a PI-3,4-P2, and which does not bind to or binds at a level of 1% or less to a phosphatidylinositol-4,5-diphosphate (PI-4,5-P2)". The features of the invention relative to what is being contacted and what is being detected to determine the presence or absence of the PI-3,4-P2 in the sample have been clarified.

New claim 22 depends from claim 21, and recites "the test sample is liquid sample".

New claim 23 is drawn to the method of claim 21 wherein the sample is "a solid sample".

New claim 24 is drawn to the method of claim 23 where the solid sample is further defined as "a tissue".

New claim 25 is drawn to the method of claim 21 where the antibody is further defined by the amino acid sequences of complementarity determining regions, CDR1 to CDR3, for each of the heavy and light chains.

New claim 26 is drawn to the method of claim 21 where the antibody is a specific monoclonal antibody produced by a hybridoma identified by the International deposit accession number.

New independent claim 27 is drawn to "a method for quantifying a phosphatidylinositol-3,4-diphosphate (PI-3,4-P2) in a test sample", where, similar to newly presented claim 21, the antibody used in the method is defined as "a monoclonal antibody labeled with a marker or a variable region thereof labeled with a marker, which specifically binds to an antigenic determinant comprising an inositol group and a glycerol backbone on a PI-3,4-P2, and which does not bind to or binds at a level of 1% or less to a phosphatidylinositol-4,5-diphosphate (PI-4,5-P2)". Likewise, the features of the invention relative to what are being contacted, what is being measured, and what is being compared to quantify the PI-3,4-P2 in the sample have all been clarified. Specifically, in the present method, the sample is contacted with the labeled antibody or the labeled variable region thereof in a container onto which a PI-3,4-P2 as a standard has been immobilized.

New claim 28 is drawn to the method of claim 27 wherein the monoclonal antibody used in the method has been further defined by the amino acid sequences of the complementarity determining regions, CDR1 to CDR3, for each of the heavy and light chains.

New claim 29 is drawn to the method of claim 27 where the antibody is limited to a specific one produced by the hybridoma cell line under the deposit.

Newly presented independent claim 30 is also drawn to a method for quantifying a PI-3,4-P2 in a sample using "a monoclonal antibody or a variable region thereof, which specifically binds to an antigenic determinant comprising an inositol group and a glycerol backbone on a PI-3,4-P2, and which does not bind to or binds at a level of 1% or less to a phosphatidylinositol-4,5-diphosphate (PI-4,5-P2)". Likewise, the features of the invention

relative to where, what are being contacted, what is being measured, and what is being compared to quantify the PI-3,4-P2 in the sample, have all been clarified. In contrast to the method of claim 27 though, according to the method of claim 30, the sample is contacted with the monoclonal antibody or the variable region thereof which has been immobilized on a container in the presence of a labeled PI-3,4-P2 as a standard.

New claim 31 is drawn to the method of claim 30 wherein the antibody being used has been defined by the amino acid sequences of the complementarity determining regions, CDR1 to CDR3, for each of the heavy and light chains.

New claim 32 is drawn to the method of claim 30 where the antibody to be used is a specific monoclonal antibody identified deposited hybridoma.

No new matter has been added by virtue of the within amendments. Support for the newly presented claims can be found throughout the specification, particularly, at page 1, lines 24-25; page 4, lines 10-12; page 10, lines 22-24; page 12, lines 10-21; page 14, line 31 to page 15, line 37; page 20, lines 27-29; page 21, lines 10-11; page 24, lines 8-10; page 24, lines 11-16; page 25, lines 1-30 (Example 4); and page 26, lines 23-31.

Entry of the referenced amendments and reconsideration of the application are requested in view of the remarks which follow.

Referring now to the Office Action, the specification is objected to because the Brief Description of the Drawings refers to Figures 7 and 8, but fails to refer to their respective sub-figures, i.e., Fig.7A through 7L and 8A through 8F. Additionally, objection is made to a typographical error appearing on page 10.

The within amendments address each of the noted informalities. For example, consistent with the priority US case (US Patent 6,709,833), the Brief Description of the

Drawings has been amended to recite the sub-figures of Figures 7 and 8 where applicable at page 7. Likewise, related text at page 26 also has been amended. Lastly, the typographical error on page 10 has been corrected.

Withdrawal of the objections to the specification is therefore requested.

The specification is further objected to under 35 USC §112, 1st paragraph, as allegedly failing to meet the written description requirements.

Additionally, claims 18 and 19 are rejected under 35 USC §112, 1st paragraph, as allegedly failing to comply with the written description and enablement requirements.

By way of history, it is noted that similar rejections were made (and overcome) in the priority US case, now US Pat. 6,709,833. Without acquiescing to the grounds for the rejection, the claims of the present application have been amended in a consistent manner as in the US priority case. For instance, Applicant submits that the antibody recited in the present method claims has been clarified similar to the proposed Examiner's amendment in the priority US case. Reference is made to the file history of the US priority case relative to this point and it is submitted that the within (consistent) amendments are sufficient to overcome the written description and enablement requirements in this divisional application.

Accordingly, it is respectfully submitted that the present specification and claims fully comply with the requirements of 35 USC 112, 1st paragraph. Reconsideration and withdrawal of the rejections are respectfully requested.

Claims 18 and 19 are rejected under 35 USC §112, 2nd paragraph, for alleged indefiniteness.

Specifically, the Examiner indicates that term of "biphosphate" should be corrected to recite either "bisphosphate" or "diphosphate". Upon entry of the proposed amendments, the newly presented claims recite "diphosphate" only. Support therefor can be found throughout the specification.

Additionally, "the antibody" recited in former claim 18 is objected to as lacking proper antecedent basis. The newly presented claims address this informality.

Further, "based on" in claim 18 is objected to and the Office Action alleges: "It is not clear how one performs the method "based on" an immunological reaction or what is intended as encompassed. The purpose of the method also is not clear as it is not clear what is being detected because in the method antibody is merely reacted with bisphosphate present in the sample."

Upon entry of the within amendments, the claimed methods have been amended to clearly define what is detected, how it is detected, determined, and/or quantified.

Still further, recitation of "the immunoassay" is objected to as lacking proper antecedent basis. The newly presented claims address this informality and recite proper antecedent basis and claim dependency.

Reconsideration and withdrawal of the rejections under 35 USC §112, 2nd paragraph, are requested.

Claims 18 and 19 stand rejected under 35 USC §102(b) over Boronenkov et al. (Molecular Biol. Cell 9: 3547, 1998). The Office Action states: "Boronenkov et al. teach an immunoassay in which phosphatidylinositol-3,4-bisphosphate-containing liposomes specifically inhibit staining with the AM-212 monoclonal antibody elicited to phosphatidylinositol-4,5-bisphosphate."

The rejection is respectfully traversed.

First, it is noted that in contrast to the position asserted, the reference, at page 3553, right column, second paragraph, lines 3-6, discloses that, "An excess of PI4,5P2 abolished the staining, whereas PI4P and PI3,4P2 at the same concentration were only partially inhibitory (Figure 8)." (emphasis added). As such, the reference teaches that the AM212 antibody is specific to the PI-4,5-P2 and little binds to the PI-3,4-P2.

Notwithstanding the disclosure by Boronenkov et al., and without acquiescing to the grounds for rejection, the newly presented claims recite methods to determine the presence or absence of, or quantify, the PI-3,4-P2 in a sample by using a labeled or unlabeled "monoclonal antibody or a variable region thereof, which specifically binds to an antigenic determinant comprising an inositol group and a glycerol backbone on a PI-3,4-P2, and which does not bind to or binds at a level of 1% or less to a phosphatidylinositol-4,5-diphosphate (PI-4,5-P2)" (emphasis added).

To anticipate a claim, each and every element of the claim must be found in a single reference. This is discussed in the Manual of Patent Examining Procedure at § 2131:

> "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the . . . claim." Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an ipsissimis verbis test, i.e., identity of terminology is not required. In re Bond, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

The cited reference does not teach or suggest all the limitations of the instant claims. The present application is clearly distinct from the art cited and the rejection is properly withdrawn.

Lastly, as noted above, new claims 26, 29, and 32 recite a hybridoma cell line identified by International deposit accession number FERM BP-6849; support therefore can be found at page 24, lines 11-16 of the specification. In view of the prosecution history for the priority US case, Applicant is aware of the possibility that an enablement rejection may be raised for reasons consistent with those asserted therein. Applicant wishes, therefore, to rely on the Declaration of April 5, 2002, filed in the priority US case to assure availability of the stated hybridoma during the patent term.

In view of the above amendments and remarks, Applicant believes the pending application is in condition for allowance.

REQUEST FOR EXTENSION OF TIME AND FEE AUTHORIZATION

Applicant hereby requests a three-month extension of time for filing the within response. Please charge all fees associated with the extension and any other required fee (or credit any overpayment) to Deposit Account No. 04-1105, Reference No. 49618DIV(71965).

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Respectfully submitted,

Electronic signature: /Christine C. O'Day/
Christine C. O'Day
Registration No.: 38,256
EDWARDS ANGELL PALMER & DODGE LLP
P.O. Box 55874
Boston, Massachusetts 02205
(617) 517-5558
Attorneys/Agents For Applicant